In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-584V
Filed: May 1, 2024

KAREN GREEN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Michael Avrim Firestone, Marvin Firestone, MD, JD and Associates, San Mateo, CA, for petitioner.
Rachelle Bishop, U.S. Department of Justice, Washington, DC, for respondent.

Findings of Fact and Conclusions of Law[1]

On May 11, 2020, the above captioned petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that a January 18, 2018 influenza ("flu") vaccination caused her to suffer a right shoulder injury. (ECF No. 1, p.1.) However, respondent contends that petitioner has not preponderantly established the fact of her allegedly injury-causing vaccination. (ECF Nos. 43, 84.) For the reasons discussed below, I now find that there is preponderant evidence that petitioner received a flu vaccination in her right deltoid on January 18, 2018.

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] Within this decision, all citations to § 300aa will be the relevant sections of the Vaccine Act at 42 U.S.C. § 300aa-10, *et seq.*

I. Factual and Procedural History

a. Initial Filings

Petitioner initially filed records marked as Exhibits 2-8. She filed a PAR questionnaire as Exhibit 10, an affidavit marked as Exhibit 1, and a photograph marked as Exhibit 9.

Exhibit 2 is a color scanned copy of a vaccine administration record completed by hand and filled in with blue ink. A yellow sticky note is affixed. It appears as follows:

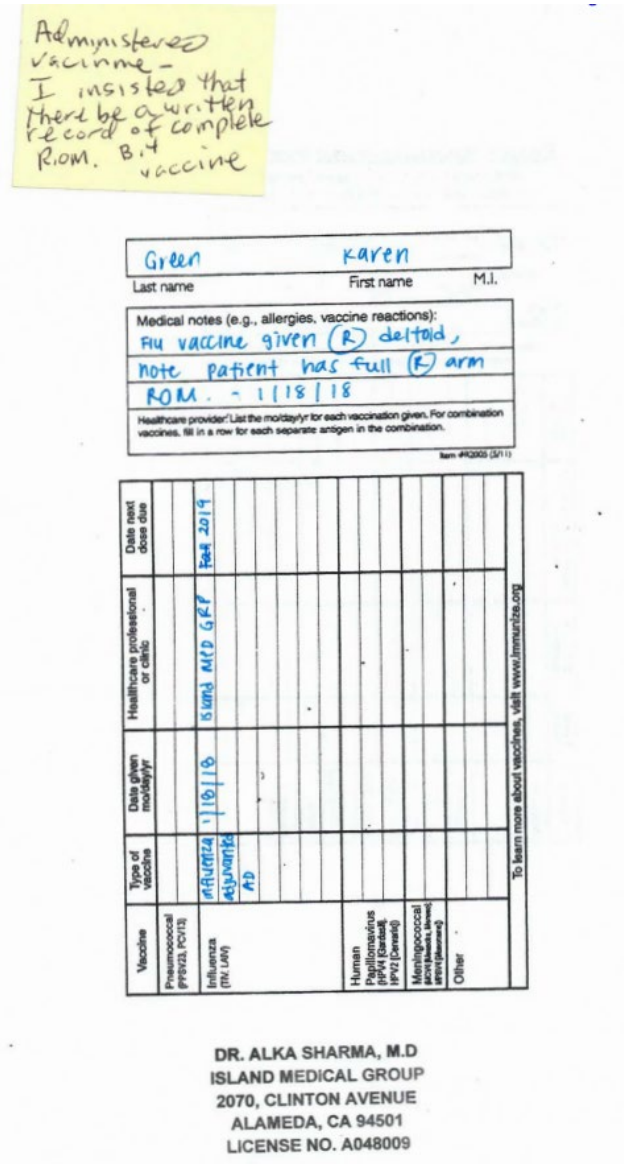


Exhibit 2 indicates that petitioner received a flu vaccine in her right deltoid on January 18, 2018. Specifically, under "medical notes," it states "flu vaccine given R deltoid, note

patient has full R arm ROM – 1/18/18." The affixed sticky note similarly states "Administered vaccine – I insisted that there be a written record of complete ROM B4 vaccine." Where prompted to indicate the type of vaccine, it indicates only "influenza adjuvanted AD" without indicating the manufacturer. The record does not indicate, nor is there any specific prompt to indicate, the manufacturer or lot number of the vaccination. The record includes a stamp indicating it is from the office of Dr. Alka Sharma, M.D., of Island Medical Group; however, there is no signature and no indication of who administered the vaccination.

Petitioner filed medical records by Island Medical Group as Exhibit 3, totaling 132 pages. These records, which include encounters dating back to 2016, are electronic medical records generated using "Practice Fusion." Exhibit 3 does not contain any copy of the handwritten form filed as Exhibit 2, nor any separately created electronic immunization record. The medical records reflect that petitioner presented for care on January 16, 2018, at which time Dr. Sharma recommended that petitioner receive a flu vaccine. (Ex. 3, p. 52.) There is no indication, however, that a flu vaccine was actually administered during that encounter. There is also no record of any encounter on January 18, 2018.

However, the medical records at Exhibit 3 also include petitioner's billing history. Petitioner was billed $135 coded 99213 on January 16, 2018. (Ex. 3, p. 3.) She was also billed $25 and $35 on January 18, 2018, coded 90686 and G0008 respectively. (*Id*.) (Petitioner subsequently filed a document from the Centers for Medicare & Medicaid Services, indicating that "90686" is the billing code for a flu vaccination. (Ex. 48, p. 2.) Respondent has not countered this point.)

Petitioner's next encounter with Dr. Sharma occurred on January 31, 2018. At that encounter, petitioner "states that following the flu vaccine, she has pain in the deltoid region and has limited range of motion in the right shoulder." (Ex. 3, p. 50.) About a week later, on February 6, 2018, petitioner sought orthopedic care. (Ex. 5, p. 58.) At that encounter, her history indicated that there were "[n]o issues until a flu shot on 1/18/18, which has led to severe pain at rest and with motion and motion loss." (*Id*.) She had an initial physical therapy evaluation on April 2, 2018. (Ex. 6, p. 120.) "She report[ed] exacerbation of pain following flu vaccination in January of this year." (*Id*.)

Petitioner's Exhibit 4 is a handwritten VAERS report prepared by petitioner and dated July 21, 2018. On this form, petitioner indicates she was vaccinated on January 18, 2018, and that her adverse event (right shoulder pain and reduced range of motion) occurred on January 19, 2018, the morning after her vaccination. She represents that the vaccine was administered at Island Medical Group. Petitioner provided the following details regarding the vaccination itself:

Vaccine: Influenza Vaccine Adjuvanted AD
Manufacturer: Pfizer
Lot number: 179603

Route: IM
Body site: R Deltoid

In her affidavit, filed as Exhibit 1, petitioner states that she received a flu vaccination at Dr. Sharma's office on January 18, 2018. Petitioner further explains that she had a prior SIRVA in her left shoulder. (Ex. 1, p. 1.) (Respondent also notes petitioner's prior SIRVA case and settlement in his motion response. (ECF No. 84, p. 1.)) Accordingly, she indicates that "I made sure to demonstrate to the nurse that I had full range of motion in my right arm prior to the injection." (Ex. 1, p. 1.) Petitioner indicates the vaccine was administered by a nurse. (*Id*.) Petitioner includes in her affidavit a photo of her right shoulder (the photo is also filed as Exhibit 9). (*Id*. at 3.) She states that she took the photo on January 20, 2018, so that she could show it to her doctors. (*Id*. at 2-3.) The photo shows a red spot over her deltoid. (*Id*. at 3.) Petitioner indicates that she completed her VAERS report "with my doctor's assistance in providing the necessary information regarding the vaccine details." (*Id*. at 5.)

b. Second Filing of Island Medical Group Records

On September 25, 2020, respondent filed a status report identifying outstanding medical records based on his counsel's review. (ECF No. 14.) In pertinent part, respondent requested petitioner file a certified copy of petitioner's vaccination record, expressing that the administration documented in the record at Exhibit 2 was not reflected in the medical records filed at Exhibit 3. (*Id*. at 2.)

Between October of 2020 and May of 2021, petitioner filed additional medical records marked as Exhibits 11-25. Exhibit 25 includes 59 pages of medical records by Island Medical Group produced in response to a subpoena from petitioner's counsel. These records appear to have been printed and faxed. Despite petitioner having specifically requested immunization records, only encounter records were provided and even those records were not complete – for example, no record of the above-discussed January 31, 2018 encounter was included. No records certification was included. No immunization record was contained within these records.

Thereafter, the parties attempted to settle the case. In the course of settlement discussions, petitioner filed a supplemental affidavit marked as Exhibit 26. Petitioner repeated the same basic account of her vaccination. (Ex. 26, p. 2.) In this affidavit, however, petitioner indicated that she "take[s] issue" with Dr. Sharma's records for a number of reasons. (*Id*. at 6-8.) In addition to asserting certain errors, petitioner alleges that Dr. Sharma has admitted to falsifying her medical records out of fear that she will be pursued by authorities over opioid prescriptions. (*Id*. at 8.) (Regardless of whether the records otherwise contain errors or inaccuracies, this particular allegation has not been substantiated.)

Unable to resolve the case informally, respondent filed his Rule 4 Report on April 11, 2022. (ECF No. 43.) Respondent argued, *inter alia*, that petitioner had not provided

preponderant proof of vaccination. (*Id*. at 26-28.) Respondent contended that the administration record at Exhibit 2 lacked sufficient indicia of authenticity and was "compromised" as an original record by petitioner's own handwritten sticky note. Respondent stressed the lack of any encounter record for the vaccination at issue and noted that petitioner could not have received a Pfizer vaccine as indicated on her VAERS report, because Pfizer did not manufacture a flu vaccine for that season. (*Id*.)

c. Filing of Island Medical Group Electronic Immunization Record

Following the filing of respondent's report, petitioner filed additional immunization records marked as Exhibit 27. Exhibit 27 consists of seven pages as follows:

- Page 1: A Fax coversheet dated April 29, 2022, from Dr. Sharma to Mr. Firestone with the subject line "Karen Green certified records and request to help clarify records."

- Pages 2-3: A letter by Mr. Firestone to Dr. Sharma dated April 29, 2022, in which he indicates that he and Dr. Sharma spoke on the phone regarding petitioner's vaccination record (which he indicates was produced by Judy Sou). The letter references three attachments, (1) the vaccination record otherwise filed in this case as Exhibit 2; (2) "a copy of the EHR Immunization Record that does list the flu vaccine's lot number, and manufacturer for the January 18, 2018 flu vaccination, but does not mention the route of administration;" and (3) a letter faxed from Dr. Sharma on April 21, 2022, confirming the accuracy of the January 18, 2018 form provided to petitioner. The letter indicates the second attachment had been provided by Dr. Sharma's office to petitioner "recently" and requests the office provide a complete set of certified medical records, including the immunization records.

- Page 4: A copy of petitioner's Exhibit 2 that appears to be the first letter attachment referenced above.

- Page 5: An EHR Immunization Record indicating a flu vaccine was administered to petitioner by Judy Sou on January 18, 2018 (manufacturer Seqirus, Lot 79603). Petitioner's age is noted to be 79 years in the header, but 74 years of age at the time of vaccination. This appears to be the second letter attachment referenced above.

- Page 6: A "Certification of Medical Records Affidavit" signed by Dr. Sharma indicating she is the custodian of records and that the attached records of January 18, 2018 are true and exact copies of petitioner's records.

- Page 7: A handwritten note on Island Medical Group letterhead addressed "to whom it may concern" and signed by Dr. Sharma on April 21, 2022, stating that "the form that was given to the patient on January 18, 2018, is accurate + issued by this practice." This appears to be the third letter attachment referenced above.

d. Dr. Sharma's Deposition

Following petitioner's filing of Exhibit 27, the case was reassigned to the undersigned. (ECF No. 50.) Petitioner subsequently filed an expert report; however, respondent indicated that he "continues to have significant concerns about the vaccination record in this case." (ECF No. 60.) In response, I noted that petitioner's Exhibit 27 appeared to include communications from Dr. Sharma purporting to authenticate petitioner's vaccination record and including sufficient information to identify the manufacturer, lot number, and (by inference) the route of administration. (ECF No. 61.) However, I indicated that "[r]ecognizing that the documentation provided in this case is irregular, the undersigned will entertain a request by respondent for authorization to pursue discovery pursuant to Vaccine Rule 7 directed to Dr. Sharma's office, potentially to include deposition(s), seeking further details regarding the circumstances of petitioner's vaccination and documentation thereof." (*Id*. at 1.)

Thereafter, respondent deposed Dr. Sharma on July 20, 2023. (Ex. A.) After Dr. Sharma's deposition was filed, the parties jointly requested a finding of fact. (ECF No. 79.) In his motion response, respondent highlights the following points from Dr. Sharma's deposition:

- Island Medical Group is a solo practice by Dr. Sharma, and Judy Sou is her only medical assistant (currently). (Tr. 11.)

- As a solo practitioner, Dr. Sharma writes her own notes and considers herself the custodian of her records. (Tr. 11, 15.)

- For the last seven years, Island Medical Group has kept electronic records, using a program called "Practice Fusion." The records are maintained electronically and stored on back up indefinitely. (Tr. 13,16.)

- Ms. Sou may transcribe notes; however, Dr. Sharma is always the author of her medical notes and her signature, which is always time- and date-stamped, confirms her review of the record. An electronic signature is generally included for every record. (Tr. 14-15.)

- However, Dr. Sharma indicated that there are some instances, such as "automatic" or "recurrent" therapeutic injections, where she may not sign off on a medical record. (Tr. 15.)

- Ms. Sou handles requests for production of records, whether by a patient or by subpoena. (Tr. 16.) Ms. Sou downloads the record, copies it, and has the patient sign for the records. (*Id*.)

- Dr. Sharma administers up to 400 flu vaccinations per year. (Tr. 12.) Island Medical Group does not use a separate vaccine consent form. Even if a patient received a vaccination without an appointment, it would be documented in their chart. (*Id.* at 13, 20.) However, it is possible for a patient to receive a flu vaccination without any corresponding appointment. (*Id.* at 42.) Dr. Sharma testified that it "would not be out of the ordinary" for petitioner to have returned for a flu vaccine a day or so after it was recommended during her office encounter. (*Id.* at 64-65.)

- Dr. Sharma indicated that Practice Fusion does include a place to record vaccinations consisting of a form that includes details, such as manufacturer and expiry date, and site of administration, and administrator. That form is completed by staff and is "[a]lmost always" completed at the time of vaccination. (Tr. 20.) The administrator does not sign the record; however, Dr. Sharma "[m]ostly" does sign off on these records in the same manner as other records. (*Id.* at 21.)

- Dr. Sharma agrees the records filed as Exhibit 25 appear to be petitioner's records; however, her former employee, Evangelina Rodriguez, likely responded to the subpoena. (Tr. 21, 23-24.) Dr. Sharma has no reason to doubt that Exhibit 25 is complete. (*Id.* at 33.)

- Dr. Sharma disputes the allegations from petitioner's supplemental affidavit and asserts that her medical notes are accurate and that any opioid prescriptions were appropriate. (Tr. 30-32.)

- Dr. Sharma was not familiar with the document at Exhibit 2 prior to preparing for her deposition. (Tr. 34.) She did not personally stamp the record at Exhibit 2, though her staff is permitted to use the stamp without approval and some loose forms may exist that have already been stamped. (*Id.* at 38, 56.) She does not know why Exhibit 2, rather than the usual electronic record, would have been produced and could not explain why the document at Exhibit 2 was not produced in response to the subpoena. (*Id.* at 34-35.) She does not know when Exhibit 2 was created. (*Id.* at 38.)

- Dr. Sharma testified that nothing like the form at Exhibit 2 has been used by her practice since they began using Practice Fusion; however, she

indicated that "it would not surprise me" if the form was included in petitioner's records. (Tr. 34-35, 55.) She testified that, at the time of petitioner's alleged vaccination, it was "not out of the ordinary" for her staff to have completed a handwritten entry. (*Id.* at 65.) Dr. Sharma acknowledged having a copy of the form filed as Exhibit 2 in her office file, but indicated that her copy of the form does not include the yellow sticky note included in Exhibit 2. (*Id.* at 39-40.)

- Dr. Sharma does not have an independent recollection of the date of petitioner's alleged vaccination. (Tr. 42.)

- Dr. Sharma agreed the electronic immunization record at Exhibit 27, page 5, was faxed to petitioner's counsel on April 29, 2022, and that the age of 79 reflected on that record is consistent with petitioner's age at the time the fax was sent. Dr. Sharma did not know when the document was created, but indicated it was "[p]robably" created in response to petitioner's counsel's request. (Tr. 45.) It is not a record signed by Dr. Sharma. Instead, "Judy would have entered that she gave the flu shot to Ms. Green. That's how this would be created." (*Id.* at 45-46.) Asked "do you have any idea if Judy entered the information on January 18th, 2018," Dr. Sharma responded "[t]hat is the standard protocol in the office."[3] (*Id.* at 46.)

- Dr. Sharma also indicated that within Practice Fusion, information regarding the expiration date and manufacturer of vaccines is automatically populated at the time the practice takes delivery of the vaccines. At the time of vaccination, only the site of administration needs to be added. (Tr. 18-21, 43, 47.)

- Ms. Sou is qualified to check range of motion, but not conduct a physical exam. (Tr. 47.) However, a range of motion test would not be typical for vaccine administration. (*Id.*)

- Dr. Sharma has no recollection of providing petitioner with details of her vaccination, but testified that it is possible her staff would honor such a request. (Tr. 48.)

- Dr. Sharma testified that she is the records custodian because she is "ultimately responsible for the records in my office." However, she could not recall what specific records she had certified in this case. (Tr. 49-50.)

[3] In his motion response, respondent characterizes this as Dr. Sharma indicating she did not know whether Ms. Sou entered the information consistent with the office protocol. (ECF No. 84, p. 9.)

- Dr. Sharma confirmed she authored the April 21, 2022 letter at Exhibit 27, page 7, and indicated the letter was based on petitioner's medical records.[4] (Tr. 51-52.)

- Dr. Sharma was not involved in the creation of petitioner's VAERS report, but she did not preclude the possibility her staff was consulted, though there is no record of such contact. (Tr. 52-54.) She has a "[v]ague[]" recollection of petitioner at some point coming into the office to ask for her vaccination record. (*Id.* at 69.)

- Dr. Sharma has never taken a recordkeeping course. (Tr. 62.)

- Dr. Sharma could not recall details of prescribing petitioner medication for headaches. (Tr. 66.)

On February 6, 2024, petitioner filed a motion for a finding of fact that she was administered a flu vaccine in her right deltoid on January 18, 2018. (ECF No. 83.) Respondent filed a response to the motion on March 21, 2024. (ECF No. 84.) Explaining that a finding against petitioner on this issue would be case dispositive, respondent cross moved for dismissal of the case. (*Id*. at 22.) Petitioner filed her reply on April 22, 2024. (ECF No. 86.) Accordingly, petitioner's motion is now ripe for resolution.

II. Legal Standard for Fact Finding

Pursuant to § 300aa-13(a)(1)(A) of the Vaccine Act, a petitioner must prove their claim by a preponderance of the evidence. A special master must consider the record as a whole but is not bound by any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. § 300aa-13(b)(1). However, the Federal Circuit has held that contemporaneous medical records are ordinarily to be given significant weight due to the fact that "[t]he records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Thus, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule is not

[4] Specifically, Dr. Sharma was asked "And how are you sure that it's accurate if you weren't the person to fill out the record and you didn't sign the record afterwards?" She responded, "No answer. You know, as I said, this is the standard of care. The patients come, they get the vaccine, the staff records it. So there is a record of her having gotten the vaccine and that's what was filled." (Tr. 52.)

absolute. Afterall, "medical records are only as accurate as the person providing the information." *Parcells v. Sec'y of Health & Human Servs.*, No. 03-1192V, 2006 WL 2252749, at *2 (Fed. Cl. Spec. Mstr. July 18, 2006). In *Lowrie*, the special master wrote that "[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." 2005 WL 6117475, at *19 (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam,* 968 F.2d 1226 (Fed. Cir. 1992)). Importantly, however, "the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance." *Murphy*, 23 Cl. Ct. at 733 (quoting the decision below).

When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, a special master must consider the credibility of the individual offering the testimony. *See Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns ex rel. Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 416-17 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence" contained in the record. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417 (concluding that the special master did not err by excluding expert opinion based on facts not substantiated by the record).

III. Party Contentions

In her motion, petitioner argues that her vaccination record at Exhibit 2, though unorthodox, is sufficient evidence she received a flu vaccination in her right deltoid on January 18, 2018. (ECF No. 83, p. 4.) She further stresses that she later produced both a letter by Dr. Sharma authenticating the form at Exhibit 2 and an EHR immunization record that additionally confirms the administrator of the vaccine, as well as the details of the vaccine (manufacturer and lot number). (*Id.*) Despite the fact that the EHR immunization record was not initially produced by Island Medical Group with the rest of petitioner's records, it was authenticated by Dr. Sharma as a true and accurate copy of a record from Dr. Sharma's office. (*Id*. at 7.)

Petitioner further argues that the fact of her vaccination is further evidenced by her contemporaneous treatment records, as well as her own VAERS submission. (ECF No. 83, pp. 4-5.) Although not all of the details contained in the VAERS report are accurate, petitioner stresses that she had the lot number correct, which would be nearly

impossible for her to have guessed.[5] Petitioner also notes that both the handwritten form at Exhibit 2 and the VAERS report indicate petitioner had received an adjuvanted flu vaccine. Petitioner represents that the Seqirus vaccine listed on the EHR immunization record was the only adjuvanted flu vaccine for the 2017-18 flu season. (*Id*. (citing Ex. 47, p. 3).) Further, the Island Medical Group records produced at Exhibit 3 show that Dr. Sharma recommended a flu vaccine at petitioner's January 16, 2018 encounter, and that the billing records show she was charged for a flu vaccine on January 18, 2018. (*Id*. at 6 (citing Ex. 3, pp. 3, 52; Ex. 48, p. 2).) It is consistent with Island Medical Group practice that petitioner's January 18, 2018 follow up to receive the vaccine did not result in a separate encounter record. (*Id*.)

In response, respondent contends that the record at Exhibit 2 is not reliable. (ECF No. 84, p. 13.) He stresses that it is not signed by Dr. Sharma or any other vaccine administrator and that it lacks documentation of the manufacturer, lot number, and route of administration, for the subject vaccine. (*Id*.) Respondent argues that Exhibit 2 is a "loose paper that bears no originating letterhead and follows no labeling convention compared to petitioner's other records from Island Medical Group" and stresses that it was not included in any of the other records produced by Island Medical Group, including in response to a subpoena. (*Id*. at 13-14.) Respondent argues that Exhibit 2, which was never certified, is legally deficient under § 300aa-25(a).[6] (*Id*. at 14.) Respondent contends Dr. Sharma had no personal knowledge of the document at Exhibit 2 prior to her deposition and that the office stamp on the document is "meaningless" because Dr. Sharma did not restrict use of the stamp by her staff. (*Id*. at 14-15.) Respondent argues that the yellow sticky note included in Exhibit 2 constitutes an "unauthorized alteration" that renders the exhibit inherently unreliable. (*Id*. at 16.) Because Dr. Sharma did not have personal knowledge regarding the creation of the document Exhibit 2, her April 21, 2022 letter purporting to authenticate the document as accurate and issued by Island Medical Group "is dubious and should not be afforded any weight." (*Id*. at 15.)

[5] In fact, petitioner acknowledges that the lot number on the VAERS form is listed as "179603" whereas the EHR immunization record does not include the "1," listing the lot as "79603." (*Compare* Ex. 4, *with* Ex. 27, p. 5.)

[6] This section sets forth requirements for medical providers for creating permanent vaccination records. While respondent is correct that Exhibit 2 is deficient in that it does not indicate the vaccine manufacturer or lot number, the sufficiency of Exhibit 2 under § 300aa-25 is not dispositive of whether petitioner has provided preponderant proof of the fact of her vaccination. Petitioners may rely on circumstantial evidence of vaccination even where there is no contemporaneous documentation available. *E.g.*, *Hydutsky v. Sec'y of Health & Human Servs.*, No. 22-753V, 2024 WL 693759, at *4 (Fed. Cl. Spec. Mstr. Jan. 18, 2024) (explaining that "[t]here are many Program cases in which direct proof of vaccine administration is missing. But when presented with sufficient preponderant circumstantial evidence – such as consistent references in contemporaneously created medical records and/or credible witness testimony – special masters have found vaccination to have occurred even without a written contemporaneous record memorializing the event."). In any event, the EHR immunization record at Exhibit 27, page 5, is consistent with § 300aa-25.

Regarding the electronic immunization record at Exhibit 27, page 5, respondent argues that it constitutes a "never-before-seen" record that presents "new" information about the vaccination at issue. (ECF No. 84, p. 16.) Respondent contends that simply including requisite information does not render the record reliable. (*Id.*) Respondent argues that neither petitioner nor Dr. Sharma have accounted for the record and Dr. Sharma has no personal knowledge about the record or its originating event. (*Id*. at 16-17.) Respondent argues that the electronic immunization record is contrary to Island Medical Group's recordkeeping practices because it was not contemporaneously created and reviewed by Dr. Sharma. (*Id*. at 17.) Respondent stresses that the document contains no separate creation date and lists petitioner's age as 79 years old, whereas she was 74 at the time of vaccination. (*Id.*) Thus, respondent contends it was a document made in response to litigation and deserving of little weight. (*Id*.)

Respondent argues that "[t]he whole of Dr. Sharma's testimony shows that she lacked personal knowledge, regulation, and oversight of how vaccines were administered or recorded in her office as well as about her office's production of requested records." (ECF No. 84, p. 18.) Respondent argues that

> [t]he documents provided in response to petitioner's counsel's communications are, at best, Dr. Sharma's blind acceptance of facts stated by petitioner in support of a lawsuit and do not amount to any more than the words of petitioner alone, unsubstantiated by medical records or by medical opinion – insufficient to prove petitioner's case as a matter of law.

(*Id*.)

Respondent is also skeptical regarding the alleged course of events. Respondent notes that the purported date of vaccination was two days following petitioner's January 16, 2018 encounter and petitioner had declined to accept recommended flu vaccinations for several years prior. (ECF No. 84, p. 13.) Moreover, the existence of the form at Exhibit 2 is contrary to what Dr. Sharma described as her office's protocols. (*Id*. at 13-14.) Respondent characterizes petitioner's range of motion test prior to vaccination as an "oddity." (*Id*. at 16.) Respondent challenges petitioner's VAERS report and also contends that the fact that petitioner was billed for a flu vaccine is "of limited worth." (Id. at 18-19, 22.) He contends the record as a whole preponderates against a finding that petitioner received any vaccination, arguing that the record evidence raises more questions than it answers. (*Id*. at 22.) He urges dismissal. (*Id*.)

In reply, petitioner argues that respondent's opposition to her proposed fact finding is unreasonable, bordering on bad faith. (ECF No. 86, p. 1.) Petitioner asserts that her medical records have been certified and there is no positive evidence of forgery, fabrication, or unlikely error. (*Id*. at 2.) Petitioner argues it would be unjust and contrary to the Vaccine Act to dismiss her claim simply because Dr. Sharma's office engaged in imperfect recordkeeping. (*Id*. at 5.) Petitioner argues that prior to any

dismissal, she should be permitted to depose Dr. Sharma's staff and/or have a live hearing. (*Id*. at 13.) Addressing respondent's suggestion that the record raises more questions than it answers, petitioner argues that respondent has at best raised some mere doubt regarding the factual question at issue. (*Id.* at 14.) However, she stresses that her burden of proof is *not* to show evidence beyond a reasonable doubt. (*Id*. at 14-15.)

IV. Analysis

I have considered the parties' arguments, as well as the record as a whole. For the reasons discussed below, I find that the vaccination records at both Exhibit 2 and Exhibit 27, page 5, are authentic. Accordingly, there is preponderant evidence that petitioner received a documented intramuscular flu vaccination manufactured by Seqirus, lot 79603, on January 18, 2018, at Island Medical Group, in her right deltoid.

Dr. Sharma confirmed during her deposition that the document at Exhibit 2 is consistent with a form her practice has used and she further authenticated the office stamp that appears on the form. (Tr. 34-35, 37-38, 55-56.) Dr. Sharma also indicated that, while the form became obsolete once the practice began using electronic records, it was still not necessarily out of the ordinary for a handwritten record to be created at the time of the vaccination at issue. (*Id.* at 65.) Although Dr. Sharma was not personally familiar with the document as filled out, there has never been any suggestion that Dr. Sharma herself administered petitioner's vaccination so such familiarity should not necessarily be expected. Dr. Sharma's testimony that the form itself and the accompanying stamp were used by her office directly answers respondent's concern that the form appeared irregular vis-à-vis Island Medical Group's other medical records.

With respect to indicia of reliability, respondent draws a distinction between the mere stamp appearing on the form and either a signature or a more formal office letterhead. (ECF No. 84, pp. 13-14.) However, especially given Dr. Sharma's recognition of both the stamp and the form on which it appears, respondent has not explained why the stamp is meaningfully different than letterhead based on Dr. Sharma's office's practices. The fact that Dr. Sharma authorized her staff to use the stamp is of no moment where the staff was likewise authorized to administer vaccinations and create vaccination records without Dr. Sharma's supervision.[7] (Tr. 15, 20-21, 35, 45-46.) In any event, this would still be similar to a letterhead. Respondent has not provided any evidence to suggest the stamp was available to individuals beyond Dr. Sharma's staff or that the staff ever misused the stamp. As respondent implies by comparison to letterhead, the stamp need not be the equivalent of a signature to assist in authentication of the document.

[7] Initially, Dr. Sharma stressed that she signs most records, including "most" vaccination records. (Tr. 15, 21.) Later, however, she indicated with respect to the electronic immunization record at Exhibit 27, page 5, that creating that vaccination record was within Ms. Sou's purview. (Tr. 44-46.)

Nor, contrary to respondent's assertion, is the sticky note included in Exhibit 2 an alteration to the record itself that would call the content of the form into question. Although the sticky note affixed to that copy of the record does seem to confirm that Exhibit 2 itself was petitioner's own copy of the record, that does not itself render the document inauthentic. Dr. Sharma confirmed that her office has a copy of the same record without the sticky note.[8] (Tr. 39-40.) Importantly, the sticky note itself is immaterial, because the notation it contains is irrelevant to the factual question at issue on this motion.

Respondent is also skeptical of the electronic immunization record produced by Island Medical Group. However, respondent likewise has not meaningfully called into question the authenticity of this document. As a threshold matter, respondent argues that Dr. Sharma lacked sufficient knowledge of petitioner's electronic immunization record to authenticate it. Importantly, however, Dr. Sharma did identify Exhibit 27, page 5, as a record from her medical practice and in keeping with her office's recordkeeping practices. (Tr. 69-71.) She only demurred on authenticating the details of the record because it would have been initially created and later produced on request by her medical assistant, Ms. Sou. (*Id.* at 44-46.) Contrary to what respondent asserts, Dr. Sharma's testimony indicates that it is consistent with office protocol for immunization records to be unsigned and unreviewed by her in at least some instances. (*Id.* at 15, 20-21, 35, 45-46.) Dr. Sharma nonetheless explained Island Medical Group's recordkeeping practices using Fusion Practice and specifically represented she felt the electronic immunization record at issue was accurate based on her knowledge of how such records are created in her practice. (*Id.* at 52.)

In finding this suspect, respondent appears to conflate being a records custodian with being an author. A records custodian vouches for the authenticity of records maintained in regular practice. That does not imply personal knowledge of the circumstances leading to the creation of each record. Even to the extent respondent feels Dr. Sharma should not consider herself a records custodian, given scope of the recordkeeping responsibilities she has delegated to her staff, Dr. Sharma can still have sufficient knowledge of the practice's recordkeeping to be a witness qualified to lay a foundation for these records regardless of whether she is *per se* the custodian of the records.[9] *Accord Conoco Inc. v. Dep't of Energy*, 99 F.3d 387, 391 (Fed. Cir. 1996)

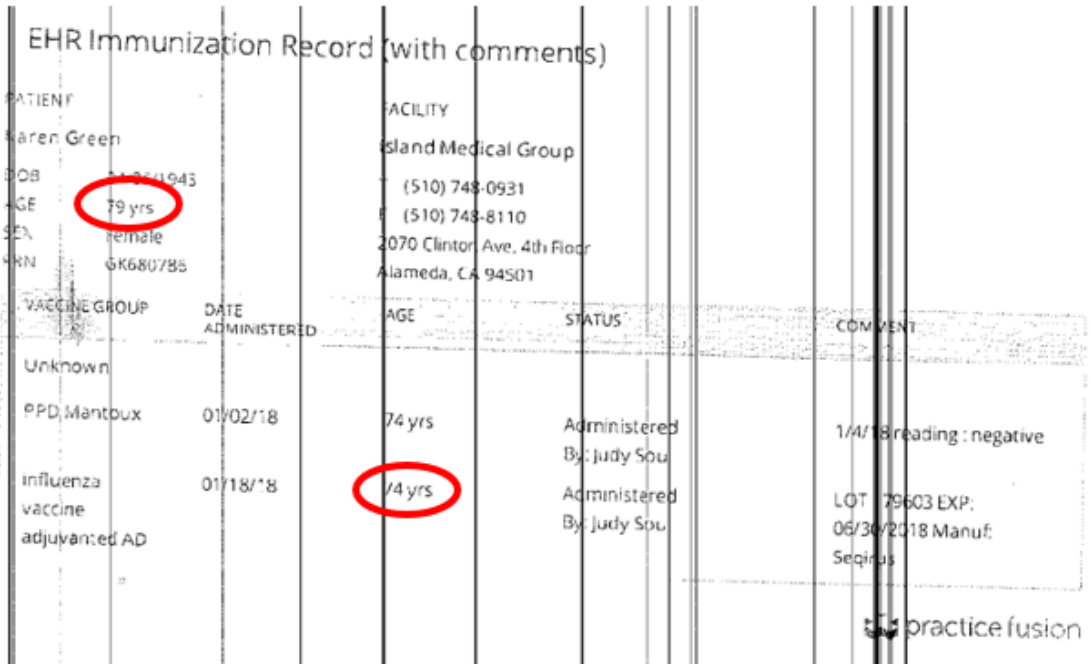
[8] Additionally, the fact that Exhibit 2 reflects a copy with original blue ink handwriting further suggests that petitioner's copy of the record is the original copy of the record. However, this is not concerning, given that Island Medical Group otherwise maintained a separate electronic immunization record. Considering the record as a whole, it is reasonable to infer that the document at Exhibit 2 was created, primarily if not exclusively, to satisfy petitioner's personal desire for documentation of her range of motion prior to vaccination. That is, given the analysis below, Exhibit 2 was likely a redundancy from the time it was created, at least as far as it serves as a vaccine administration record.

[9] Notably, my order advising that I would entertain a request for discovery by respondent did not limit respondent to deposing Dr. Sharma. (ECF No. 61.) Respondent never sought any opportunity to seek the testimony of Ms. Sou or any other member of Dr. Sharma's staff he felt was more knowledgeable with respect to maintaining the practice's records and responding to requests for production.

(stating with respect to Federal Rule of Evidence 803(6) that "[c]ourts have made clear, however, that the 'custodian or other qualified witness' who must authenticate business records need not be the person who prepared or maintained the records, or even an employee of the record-keeping entity, as long as the witness understands the system used to prepare the records"). Respondent has in no way substantiated his bold assertion that Dr. Sharma's records and testimony reflect only "blind acceptance of facts stated by petitioner in support of a lawsuit." (ECF No. 84, p. 18.) Moreover, respondent has not come forward with any evidence that would suggest Dr. Sharma is anything other than a disinterested witness. (Tr. 25.)

Respondent raises two more specific reasons explaining his doubt of the authenticity of the electronic immunization record. First, this record was not produced within the previously filed records by Island Medical Group. Second, the header on the document lists petitioner's age as 79 – her age at the time the record was faxed, rather than at the time of the alleged vaccination. Taking these points together, respondent presumes the electronic immunization record was first created at the time it was faxed, *i.e.*, years after petitioner's vaccination. However, this amounts merely to speculation and is not ultimately persuasive.

Respondent is correct to note that the EHR immunization record includes two separate ages for petitioner as shown in the image below:


EHR Immunization Record (with comments)

PATIENT
Karen Green
DOB
AGE 79 yrs
SEX female
MRN GK680785

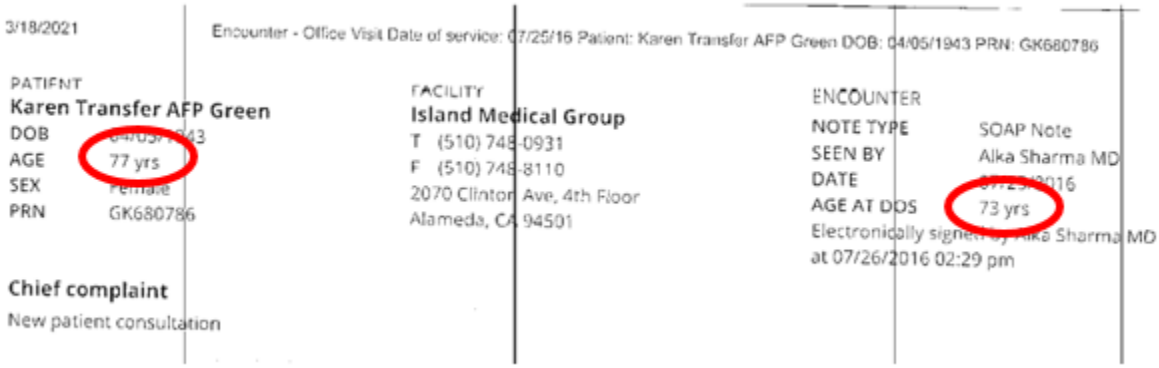
FACILITY
Island Medical Group
(510) 748-0931
(510) 748-8110
2070 Clinton Ave, 4th Floor
Alameda, CA 94501

VACCINE GROUP	DATE ADMINISTERED	AGE	STATUS	COMMENT
Unknown				
PPD Mantoux	01/02/18	74 yrs	Administered By: Judy Sou	1/4/18 reading : negative
influenza vaccine adjuvanted AD	01/18/18	74 yrs	Administered By: Judy Sou	LOT 29603 EXP: 06/30/2018 Manuf: Seqirus

practice fusion

(Ex. 27, p. 5.) As respondent stresses, this document includes a header of patient information that lists petitioner's age as 79, consistent with the date of production having been in 2022, whereas the body of the record notes petitioner's age at the time of her vaccination in 2018 to have been 74. (*Id.*) (On the above image, these references to

petitioner's age have been circled by the undersigned.) Importantly, however, this is not unique to petitioner's vaccination record. The medical records reflect that Practice Fusion is a cloud-based recordkeeping program (*e.g.*, Ex. 3, p. 74 (noting it to be a "free cloud based EHR"), and Dr. Sharma specifically testified that the records must be downloaded at the time they are requested (Tr. 16). And, as respondent acknowledges in his motion response, the records at both Exhibit 27 and Exhibit 25 appear to have been printed and faxed to counsel. (ECF No. 84, pp. 17, 21.) This appears to be the most likely explanation for the age discrepancy on the immunization record, given that the same discrepancy appears throughout the medical records produced within Exhibit 25, which were printed and faxed in response to petitioner's subpoena. Note, for example, the header on petitioner's July 25, 2016 encounter record at Exhibit 25, page 5:



This record indicates in the rightmost column that, on the date of service, July 25, 2016, petitioner was 73 years old. However, in the leftmost column, petitioner's age is listed within the patient demographics as 77, which corresponds to what appears to be the March 18, 2021 date of download bannered at the top left of the page.[10] (Ex. 25, p. 5.) (On the above image, these references to petitioner's age have been circled by the undersigned.) Although Exhibit 25 is not complete, respondent does not dispute that petitioner actually had medical encounters on the dates of service reflected throughout these records. Accordingly, based on how the Island Medical Group records appear as a whole in Exhibit 25, the age discrepancy does not readily call into question that the electronic immunization record was created at the time of vaccination. Although unusual, the presence of two separate ages on petitioner's EHR immunization record appears to simply be a quirk of the recordkeeping software used by Island Medical Group under at least some circumstances.[11]

[10] On March 26, 2021, petitioner filed a status report confirming that Island Medical Group had received petitioner's records request and was at that time still working on responding. (ECF No. 24.)

[11] The medical records petitioner initially filed from Island Medical Group as Exhibit 3 do not include the same age discrepancy. However, for these records, the date bannered in the top left corner of each encounter record corresponds, within about a day or so, to the date of service. The records at Exhibit 25 appear to have been printed and faxed whereas petitioner's records request within Exhibit 3 was pursuant

Given that the electronic immunization record is not facially suspect and has been authenticated by Dr. Sharma, the fact that it was omitted from the records produced in response to petitioner's subpoena (Exhibit 25) is not dispositive standing alone. Without other factors, respondent is not persuasive in suggesting that the belated filing of this document renders it a "new" record. (ECF No. 84, pp. 16-17.) In the undersigned's experience, it is not unheard of for some medical practices to omit ancillary records, such as immunization records or telephone encounter records, from requested records or to simply err the production of records. Here, petitioner did later specifically request petitioner's immunization records; however, as discussed above, Island Medical Group's production of records in response to petitioner's subpoena was clearly incomplete and, given petitioner's specific request, non-responsive. Exhibit 25 only included encounter records and did not even include all of petitioner's encounters. Even setting aside the EHR immunization record, Dr. Sharma acknowledged that the practice had maintained a copy of the handwritten vaccine administration record at Exhibit 2; yet, that record was likewise not produced within Exhibit 25. Notably, Dr. Sharma explained that the employee who responded to petitioner's subpoena was "problematic" and had been subsequently terminated. (Tr. 22-23.) Given the overall deficiencies of the records production, the absence of the EHR immunization record from the records production does not raise a suspicion that the record did not exist at the time of production. This omission might have been more meaningful had respondent actually substantiated his concern regarding the age discrepancy on the face of the electronic immunization record. However, as discussed above, he is unpersuasive on that point.

Respondent also finds it suspicious that petitioner would have received a vaccination without any corresponding encounter record. However, Dr. Sharma's testimony confirmed this is possible based on the way her practice operates. (Tr. 13, 20, 42, 64-65.) Moreover, petitioner's medical records do confirm that she was billed for a flu vaccination on January 18, 2018. (Ex. 3, p. 3; Ex. 48, p. 2.) Furthermore, petitioner's subsequent medical treatment records show that she was consistent in attributing her right shoulder injury to her vaccination when seeking care from multiple providers. (Ex. 3, p. 50; Ex. 5, p. 58; Ex. 6, p. 120.) This has been accepted in prior cases as some evidence supporting the fact of administration in the affected shoulder. *E.g.*, *Hydutsky*, 2024 WL 693759, at *4; *see also Gambo v. Sec'y of Health & Human Servs.,* No. 13-691V, 2014 WL 7739572, at *3-4 (Fed. Cl. Spec. Mstr. Dec. 18, 2014); *Lamberti v. Sec'y of Health & Human Servs.,* No. 99-507V, 2007 WL 1772058, at *7 (Fed. Cl. Spec. Mstr. May 31, 2007). *But see Matthews v. Sec'y of Health & Human Servs*., No. 19-414V, 2021 WL 4190265, at *6-7 (Fed. Cl. Spec. Mstr. Aug. 19, 2021), *motion for review denied*, 157 Fed. Cl. 777 (2021). Although neither of petitioner's

to the HITECH Act and specifically requested electronic copies only. (Ex. 3, p. 1.) On the current record, it is impossible to discern why exactly these age discrepancies occur in some records productions and not others. But regardless, there is enough information on this overall record to reasonably conclude that the age discrepancy in the header of the electronic immunization record does *not* imply that the electronic immunization record was first created when petitioner was 79 years old.

vaccination records specifies that it was an intramuscular vaccine, Dr. Sharma testified that her office does not offer any intradermal flu vaccinations. (Tr. 19.)

I have considered respondent's remaining arguments. However, because I find no reason to question that the vaccination records at Exhibit 2 and Exhibit 27, page 5, are authentic, the remainder of respondent's arguments are either unavailing or immaterial.

V. Conclusion

In light of the above, there is preponderant evidence that petitioner received an intramuscular flu vaccination manufactured by Seqirus, lot 79603, on January 18, 2018, at Island Medical Group, in her right deltoid.

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master